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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,909	06/26/2003	Michael E. Leckrone	P0008030.03	5688
27581	7590	10/11/2007		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER EREZO, DARWIN P	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 10/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/606,909

Applicant(s)

LECKRONE ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-41 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39, 41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in the reply filed on 7/26/07 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 40 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 7/26/07.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 39, 41 and 43-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-19 of U.S. Patent No. 6,613,062. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the structural limitations disclosed in the application is also disclosed in the patent. For example, both the application and patent disclose an apparatus having an outer tubular body with inwardly directed projections; an inner tubular member having outwardly directed projections; wherein said projections form an interlocking mechanism. The difference between the application and the patent lies with the limitations of a first and second frustoconical flanges and a fluid delivery catheter as part of the apparatus. The patent fails to provide teachings for these limitations.

However, it would have been obvious matter of design choice to modify the apparatus of the application to have frustoconical flanges since the applicant has not disclosed that frustoconical flanges solve any stated problem or is used for any particular purpose. Thus, one of ordinary skill in the art would have expected the flange of the application and the frustoconical flange of the patent to perform equally as well.

It also would have been obvious to provide a delivery catheter to the apparatus of the patent because the claimed invention of the patent is directed towards an apparatus for delivery a "medical device", such as a delivery catheter, to a desired location.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 39, 41 and 43-45 are rejected under 35 U.S.C. 103(a) as being

unpatentable over 5,672,158 to Okada et al.

Figs. 1-7 of Okada disclose a prior art device having an elongated outer tubular body **2** having a lumen **17** with an inner surface provided with inwardly directed projections (see Fig. 5) spaced from one another around the circumference of the lumen and defining recesses **18** between them; an elongated inner tubular member **3** coaxially nested within the lumen of the outer tubular body and having an outer surface provided with outwardly directed projections **20** spaced from one another around the circumference of the inner tubular member and defining recesses between them; a locking mechanism comprising the combination of the inwardly directed projections of the outer tubular body and the outwardly directed projections of the inner tubular member; a ribbed flange carried at the distal end of the elongated inner tubular member (Fig. 8); and a second frustoconical flange carried at the distal end of the elongated outer tubular body (see the tapering of element **2** on Fig. 4), and a catheter **8**, wherein

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the device is fully capable of being used to access the pericardial space, and wherein the projections are spaced at 90 degrees from one another.

Okada fails to disclose the first flange of the inner tubular member being frustoconical and being oppositely directed from the second flange, and wherein the projections from are spaced at 120 degrees from one another. However, it would have been an obvious matter of design choice to modify the first flange of Okada to have a frustoconical shape, or for the projections to be spaced at 120 degrees from one another, since applicant has not disclosed that the flange with such specific shape or orientation solve any stated problem or is used for any particular purpose. Furthermore, one of ordinary skill in the art would have expected Okada's apparatus to perform equally as well with a frustoconical flange or with the projections at 120 degrees.

It should be further noted that limitations in the claim which presents no novel or unexpected result over a similar feature used in the prior art references, and solved no stated problem, were held to be an obvious matter of design choice within the skill of the art. In re Kuhle, 526 F2d 523; 188 USPQ 7 (CCPA 1975). In re Gazda, 42 CCPA 770; 219 F2d 449; 104 USPQ 400 (1955). In re Launder, 42 CCPA 886; 222 F2d 371; 10 USPQ 446 (1955).

Okada discloses the projections of either the inner tubular member or the outer tubular member to be disposed concentrically as a ring. Okada is silent with regards to a plurality of these rings. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a plurality of projections in the form of a ring, since it has been held that mere duplication of the essential working parts of a

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device involves only routine skill in the art. *In re Harza*, 274 F.2d, 669, 124 USPQ 378 (CCPA 1960).

Response to Arguments

8. Applicant's arguments filed 7/26/07 have been fully considered but they are not persuasive.

The double patenting rejection based on US 6,613,062 is maintained for the reasons indicated in the rejection above.

9. Applicant's arguments with respect to claims 39, 41 and 43-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/
Examiner
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